UPDATE
from the National Center for Ethics in Health Care

Spring 2006

The National Center for Ethics in Health Care is VHA's primary office for addressing the complex ethical issues that arise in patient care, health care management, and research.

Our mission is to clarify and promote ethical health care practices throughout VHA and nationwide. The Center supports clinical, organizational, and research ethics by:

- providing ethics consultation to VHA leaders and field-based ethics programs on request
- developing and interpreting VHA national policies concerning health care ethics
- developing and delivering educational programs
- creating and administering tools to evaluate the quality of ethics programs and practices across VHA
- publishing ethics-related news, events, best practices, cases, and feature articles

National Center for ETHICS in Health Care

FEATURED — iMedConsent
Improving Informed Consent across VHA

Electronic support for patient decisions is taking root across VHA. Since the end of FY 2005 *iMedConsent*, a software application designed to improve the quality of informed consent for clinical treatments and procedures, has been available at all VA medical centers. Usage is steadily increasing across the system, not least because *iMedConsent* now offers patient education materials and support for informed consent across 28 clinical specialties, with more in development. How is *iMedConsent* changing informed consent practices in VHA?

Informed consent on record

One way to think about *iMedConsent*'s impact is to look at the numbers. From October 1, 2005 through March 31, 2006, use of the program increased some 40 percent across the system as a whole. This represents nearly 208,000 procedures. Perhaps not surprisingly, over this period consent forms were saved directly to CPRS most frequently for procedures in specialties for which *iMedConsent* was first piloted in VA: gastroenterology (18,567 consents in CPRS), urology (7, 066), cardiology (6,545).

Ensuring best practice

Of course, numbers only tell part of the story. *iMedConsent* is intended to promote shared decision making and the tool's more significant impact has been its effect on informed consent practices throughout VHA. By walking clinicians and patients through the *process* of informed consent, *iMedConsent* has highlighted for facilities where their practices fall short.

Such news isn't always the most welcome, but it is leading to improved health care practices overall. For example, because it captures signed consent forms directly into CPRS, *iMedConsent* streamlines workflow and ensures that consent forms

No. of Consents	
VISN*	FY06/Qtr2
1	8,761
2	4,007
3	10,402
4	10,785
5	6,629
6	16,975
7	16,651
8	14,849
9	12,187
10	4,852
11	4,259
12	15,935
15	11,697
16	18,517
17	10,867
18	12,703
19	3,620
20	2,162
21	4,272
22	8,051
23	9,602

*Data for individual facilities are available at http://vaww.patientdecisions.va.gov/docs/imed_report_0506.xls

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Staff News

Ethics Center staff regularly participate in conferences and programs within VHA and with outside audiences. Below are highlights of recent activities.

In February Ethics Center Director Ellen Fox, MD, was one of two Americans invited to participate in a day-long "think tank" on ethical decision making for Local Health Integration Networks (LHINs) in Ontario, Canada. Dr. Fox, Norman Daniels, professor of ethics at Harvard University, and colleagues from Canada and the United Kingdom shared current research on ethical decision making and priority setting in health care. The session offered guidance for developing an ethical framework for decision making by LHIN chairs and CEOs.

New Deputy Director Joins Ethics Center

Sherrie Hans, PhD

On May 1st Sherrie Hans, PhD, joined the National Center for Ethics in Health Care as Acting Deputy Director. Dr. Hans, who holds a PhD in biochemistry from the University of California – San Francisco, most recently served as program director in the former Office of the Deputy Under Secretary for Health for Health Policy Coordination. In that capacity she was responsible for initiating and managing health policy projects that extended to other federal agencies and outside groups, with a particular focus on partnership opportunities with the Department of Health and Human

From the Director

Two years ago, after extensive review and pilot testing, the Ethics Center recommended that VHA implement *iMedConsent*, a software application designed to support patient decision making and improve the informed consent process. Today, the tool is up and running at every VA medical center in the country.

Meanwhile, the Ethics Center is continually working to enhance the functionality of the program. From an initial four content areas *iMedConsent* has expanded to provide support in 28 clinical specialities—and the Office of Patient Care Services is reviewing additional specialities for future integration into *iMedConsent*'s clinical library. New templates are being developed for advance directives and consent for shared medical appointments. And a special project is underway to translate *iMedConsent* materials into Spanish.

iMedConsent helps to improve ethics quality not only by standardizing informed consent practices at the level of individual patient decisions. It is also helping to identify opportunities to clarify and improve national policy—through queries to our *iMedConsent* project manager as well as requests to our ethics consultation service. The result is better informed consent policy and practices across our system.

Consultation Notes

The Ethics Consultation Service of the National Center for Ethics in Health Care responds to inquiries from VHA staff. To request a consultation send an email to vhaethics@va.gov.

Many of you know the ethics consultation service because your facility has requested a consultation seeking ethical analysis and guidance. But that is only one of the ways the service helps to ensure that veterans receive the highest quality health care. The consultation service also plays an important role in helping to interpret national VHA policies relating to health care ethics—and in helping the center to identify areas in which policy can be clarified and systems improved.

Because no policy can anticipate every circumstance in which it will apply, questions will always arise about how to understand policy requirements in specific situations. Many times such questions come to the Center first in the form of requests for consultation. For example, one recent consultation request asked for clarification about whether separate consent is required each time treatment is repeated for the same diagnosis, such as chemotherapy or dialysis.

Some policy questions initially raised with the Center's

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Staff News – cont'd

Services. Under a memorandum of agreement with the Indian Health Service, she took the lead in developing activities and programs to enhance services to American Indian and Alaska Native veterans.

In addition to representing the Ethics Center and the Director within and outside VA, as Deputy Director, Dr. Hans will manage the center's portfolio of national policy relating to health care ethics. She will provide operational leadership for the Center and will play a key role in promoting and leading collaborations with other national program offices within VHA.

Dr. Hans brings a distinguished background in health policy. Before joining VA in 2003, she served as Senior Health Policy Advisor in the Office of Public Health and Science, Office of the Assistant Secretary for Health, Department of Health and Human Services, providing analysis on issues ranging from xenotransplantation to health care quality improvement and information technology.

As program officer for health and human services for The Pew Charitable Trusts from 1998 to 2001, Dr. Hans was responsible for developing national grant-making strategies as well as managing a portfolio of grants covering leadership development in biomedical science, cognitive neuroscience research, agricultural biotechnology and bioethics, among other areas.


"Pounce"

Dr. Hans lives in Alexandria, Virginia, with her husband, Dr. David Bowen, and "Pounce," who is responsible for bug management policy in the household's award-winning garden.

Consultation Notes – cont'd

Ethics Consultation Service have given rise to publications, such as the December 2004 *Ethics Rx* on consent for HIV testing. Others have prompted the Center to develop educational programs—e.g., a National Ethics Teleconference on the ethics of shared appointments (October 2005). Still others have led to the development of stronger practices and new tools—such as enhanced disclosure practices for shared medical appointments, which will be supported by a new *iMedConsent* template now in design.

Questions to the consultation service have also helped to identify policy gaps. For example, how to document signature consent when a patient lacks the physical ability to sign or mark an "X" on the consent form. Current policy allows patients who are not literate to mark an "X" in the signature box on the form, but does not provide guidance for appropriate procedure when a patient is physically unable to hold a pen/stylus. Revisions now underway to Handbook 1004.1, *Informed Consent for Clinical Treatments and Procedures*, will set standards for practice in VA on this point.

"iMedConsent"– cont'd

are available when and where they are needed. And we're hearing that *iMedConsent* is helping to improve patient education about and understanding of procedures—like the patient who at first thought he was undergoing an unfamiliar procedure when he gave consent for a repeat sigmoidoscopy, because he found the description in *iMedConsent* so much more thorough and understandable than previous explanations had been.

> My experience has been very rewarding. Using the program saves time—everything is there for the discussion with the patient. The standardization is very good. It avoids the possibility of omitting important information.
>
> Rahim Asgard, MD, Urology
> Marion VA MC, Marion, Illinois

Feedback from the field about *iMedConsent* has also led to quality improvement activities at the Ethics Center in the form of efforts to critically review and clarify or amend national policy. For example, we're pursuing regulatory change to extend the validity of a signed consent form from 30 to 60 days to make it more feasible to have these consent conversations well in advance of a treatment or procedure, when clinicians and patients have time for careful discussion.

Expanding the vocabulary of informed consent

iMedConsent itself is an ongoing exercise in quality improvement. The National Center for Ethics in Health Care is working with the application's developer, Dialog Medical, to enhance both functionality and content. One of the most significant enhancements will be the addition of Spanish-

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Looking Ahead

National Ethics Teleconferences

1-800-757-1750
28410#

June 27, 2006
Tuesday – 12-1pm ET

July 26, 2006
Wednesday – 1-2pm ET

September 26, 2006
Tuesday – 12-1pm ET

Topics will be announced in advance of each call by email notice and at http://vaww1.va.gov/vhaethics/networking_6.cfm.

National Ethics Committee

At its January 12, 2006 meeting, VHA's National Ethics Committee (NEC) identified the following topics for future reports:

- ethical issues in advance care planning for mental health
- ethics of reporting impaired drivers to state licensing agencies and others

NEC reports identify current controversies, summarize relevant ethical and professional standards, and provide ethical analysis in arriving at reasonable, relevant recommendations for clinical and managerial practice. When appropriate, NEC reports are intended to stimulate needed policy changes identified by the Committee.

The National Center for Ethics in Health Care welcomes your feedback on *Update*. Let us hear from you—send your comments to vhaethics@va.gov.

Perspective — Performance Monitors for iMedConsent

VA is committed to providing high quality health care for America's veterans and recognizes that informed consent is essential to achieving that goal. Thus in 2004 VHA's National Leadership Board mandated implementation of *iMedConsent* in all VA medical centers to improve the quality of informed consent system wide.

With national installation now complete (in September 2005), performance monitors have been established. The goal for each facility is to implement *iMedConsent* in 2–4 specialties per quarter, resulting in regular and routine use in at least 10 clinical specialties within one year of installation. All clinical specialties should be using *iMedConsent* within two years of installation. VISNs are expected to report progress on a quarterly basis, indicating whether *iMedConsent* has been implemented and whether it is being used regularly.

It's important to remember that in addition to meeting these goals for implementing *iMedConsent* in all clinical specialties for which it is available, facilities should work to ensure that practitioners use the program's standardized consent forms wherever those exist.

"iMedConsent"– *cont'd*

language materials, which six facilities began beta testing in April. These new materials include consent documents, education materials, and patient instructions for tests and admissions. The first Spanish content—41 individual documents—covers cardiology, gastroenterology, general surgery, and urology, as well as consent for HIV testing.

iMed – *Cardiology in Spanish*

Consent Documents
- Heart – Exercise Tolerance Test
- Heart – ETT Stress Echo

Standard Education Documents
- Heart Attack – Warning Signs
- Myocardial Infarction

Easy Reading Education Documents
- Eating Heart Health Way
- High Blood Pressure

Patient Instructions
- Stress Test Exercise
- Stress Test w/Echo

In itself, *iMedConsent* cannot guarantee shared decision making or create an ethical environment in which strong informed consent practices are second nature throughout the organization—those broad goals require the ongoing efforts of clinicians, managers, and staff across our system. But *iMedConsent is* a valuable tool to support those efforts by making it easier for VHA practitioners to do the right thing.